

**IN THE UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

**IN RE:**

## FOSAMAX PRODUCTS LIABILITY LITIGATION

***This Document Relates To:***

**LEONIE ROTHLEDER**

**PLAINTIFF,**

**1:06-MD-1789 (JFK)**

**-VS.-**

**Cause No. 1:07-cv-9817**

**MERCK & CO., INC.**

**DEFENDANT.**

**PLAINTIFF'S ORIGINAL PERSONAL INJURY COMPLAINT  
AND DEMAND FOR JURY TRIAL**

COMES NOW Plaintiff Leonie Rothleder, and for her Original Personal Injury Complaint and Demand for Jury Trial against Defendant Merck & Co., Inc., alleges and avers as follows:

## PRELIMINARY STATEMENT

1. This is a proceeding brought by Plaintiff seeking damages for personal injuries suffered as a result of the Plaintiff's ingestion of a dangerous pharmaceutical product "Fosamax"®<sup>1</sup> (alendronate sodium; hereinafter "Fosamax"), which was

<sup>1</sup> Fosamax is the registered trademark of Defendant Merck & Co., Inc.

continuously manufactured, marketed, advertised, and distributed to the general public by Defendant Merck & Co., Inc.

## **PARTIES**

### **PLAINTIFF:**

2. Plaintiff Leonie Rothleder was a citizen and resident of the State of New York at the time the instant cause of action arose and is a citizen of the State of York at the time of filing this action. Plaintiff resides in Bellerose, Nassau County, New York.

### **DEFENDANT**

3. At all times mentioned, Defendant Merck & Co., Inc., (hereinafter "Merck") was and is a corporation incorporated, operating and existing under the laws of incorporation, of the State of New Jersey, with its principal place of business at One Merck Drive, P.O. Box 100, Whitehouse Station, New Jersey. At all times herein mentioned, Defendant Merck, in interstate commerce and in this judicial district, purposefully marketed, designed, manufactured, tested, analyzed, distributed, recommended, merchandised, advertised, promoted, supplied and sold to distributors, and retailers for resale to physicians, hospitals, medical practitioners and the general public, a certain pharmaceutical product, hereinafter referred to as Fosamax. At all times herein mentioned, the Defendant Merck was the actor engaged in the acts herein alleged, acting through its agents and employees, and at all times, the actions and omissions asserted in this pleading were committed by agents or employees acting within the purpose and scope of said agency and/or employment, and/or all of said acts and conduct were ratified and approved by said Defendant.

## **JURISDICTION AND VENUE**

4. Jurisdiction is proper in this court pursuant to 28 U.S.C. §1332 for the reason that there is complete diversity of citizenship between Plaintiff and Defendant and the matter in controversy greatly exceeds the sum of seventy-five thousand dollars (\$75,000.00) exclusive of interest and costs.

5. Venue is proper in this judicial district pursuant to Case Management Order No. 3.

### **SUMMARY OF THE CASE**

6. Merck, either directly or through its agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed and/or sold Fosamax for the treatment of osteoporosis, prevention of bone loss, Paget's Disease, among other uses.

7. As a result of the defective nature of Fosamax, persons who were prescribed and ingested Fosamax, including Plaintiff, have suffered and may continue to suffer severe and permanent personal injuries, including without limitation, one or more of the following: bisphosphonate induced osteonecrosis and/or osteochemonecrosis of the jaw.

8. Merck concealed its knowledge of Fosamax's unreasonably dangerous risks from Plaintiff, other consumers, and the medical community. Defendant Merck failed to conduct adequate and sufficient post-marketing surveillance of Fosamax after it began marketing, advertising, distributing, and selling the drug.

9. As a result of Defendant's actions and inaction, Plaintiff was injured due to ingestion of Fosamax, which has caused and will continue to cause her various injuries and damages. Plaintiff accordingly seeks compensatory damages and other damages.

### FACTUAL ALLEGATIONS

10. At all relevant times, Defendant Merck was responsible for, or involved in, designing, manufacturing, marketing, advertising, distributing and selling Fosamax, as detailed below.

11. In September 1995, the United States Food and Drug Administration ("FDA") approved Merck's compound alendronate for various uses, including the treatment of osteoporosis and Paget's Disease. Alendronate is marketed by Defendant Merck as Fosamax.

12. Fosamax falls within a class of drugs known as bisphosphonates. Bisphosphonates are used for treating bone conditions such as osteoporosis and Paget's Disease. Other drugs within this class, such as Aredia and Zometa, are used as chemotherapy and as adjunct chemotherapy but are not indicated for use in non-cancerous conditions such as osteoporosis.

13. There are two classes of bisphosphonates: the N-containing (nitrogenous) and nonN-containing (non-nitrogenous) bisphosphonates. The nitrogenous bisphosphonates include the following: pamidronate (Aredia); ibandronate (Bondronat); and alendronate (Fosamax). The non-nitrogenous bisphosphonates include the following: etridonate (Didronel); clodronate (Bonefos and Loron); and tiludronate (Skelid). Alendronate contains a nitrogen atom. The Physicians Desk Reference ("PDR") for Fosamax confirms that the molecule contains a nitrogen atom.

14. Throughout the 1990s and 2000s, medical articles and studies appeared reporting the frequent and common occurrence of bisphosphonate induced osteonecrosis and/or osteochemonecrosis of the jaw within the nitrogenous bisphosphonates used for

chemotherapy. As with its reported and acknowledged side effects concerning irritation, erosion and inflammation of the upper gastrointestinal tract, Merck knew or should have known that Fosamax, as a nitrogenous bisphosphonate, shared a similar adverse event profile to the other drugs within this specific subclass of bisphosphonates (i.e., those containing nitrogen).

15. Merck also knew or should have known<sup>2</sup> that bisphosphonates, including Fosamax, inhibit endothelial cell function. Similarly, Merck knew or should have known that bisphosphonates also inhibit vascularization of the affected area and induce ischemic changes specific to patients' mandibles (lower jaws) and maxillae (upper jaws) and that these ischemic changes appear to be cumulative in nature.

16. Merck also knew or should have known that these factors combine to create a compromised vascular supply in the affected area. As a result, a minor injury or disease can turn into a non-healing wound. That, in turn, can progress to widespread necrosis (bone death) and osteomyelitis (inflammation of bone marrow).

17. Dentists are now being advised by dental associations to refrain from using any invasive procedure (such as drilling a cavity) for any patient on Fosamax.

18. Once the osteonecrosis begins and becomes symptomatic, it is very difficult to treat and typically is not reversible.

19. Shortly after Defendant began selling and distributing Fosamax, reports of bisphosphonate induced osteonecrosis and/or osteochemonecrosis of the jaw and other dental complications among users began surfacing, indicating that Fosamax shared the class effects of the other nitrogenous bisphosphonates. Despite this knowledge, Merck

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<sup>2</sup> Throughout this Complaint, whenever Plaintiff asserts Merck "should have known," Plaintiff is asserting that the dangerous propensity of Fosamax was knowable to Merck given the accepted scientific knowledge at the time of manufacture and distribution.

failed to implement further study of osteonecrosis and/or osteochemonecrosis of the jaw relative to Fosamax. Rather than evaluating and verifying the safety of Fosamax with respect to bisphosphonate induced osteonecrosis and/or osteochemonecrosis of the jaw, Defendant proposed further uses of Fosamax, such as Fosamax-D, and sought to extend the exclusivity period of Fosamax through 2018.

20. Bisphosphonate induced osteonecrosis and/or osteochemonecrosis of the jaw is a serious medical event and can result in severe disability and death.

21. Rather than warn patients, and despite knowledge of an increased risk of bisphosphonate induced osteonecrosis and/or osteochemonecrosis of the jaw on patients using Fosamax, Merck continued to defend Fosamax, mislead physicians and the public, and minimize unfavorable findings.

22. Fosamax is one of Defendant's top selling drugs, averaging more than \$3 billion a year in sales.

23. Consumers, including Plaintiff, who have used Fosamax for the treatment of osteoporosis, have several alternative safer products available to treat the conditions.

24. Merck knew of the significant risk of dental and oral complications caused by ingestion of Fosamax, but did not adequately and sufficiently warn consumers, including Plaintiff, or the medical community, of such risks.

25. In an elaborate and sophisticated manner, Merck aggressively marketed Fosamax throughout the United States. This marketing was directed to consumers and medical professionals (including physicians and leading medical scholars) in order to leverage pressure on third party payers, medical care organizations, and large institutional buyers (e.g., hospitals) to include Fosamax on their formularies. Faced with the

increased demand for the drug by consumers and health care professionals that resulted from Merck's successful advertising and marketing blitz, third party payers were compelled to add Fosamax to their formularies. Merck's marketing campaign specifically targeted third party payers, physicians, and consumers, and was designed to convince them of both the therapeutic and economic value of Fosamax.

26. As a direct result, Plaintiff was prescribed Fosamax and has been permanently and severely injured, having suffered serious consequences from the ingestion of Fosamax. Plaintiff requires and will in the future require on-going medical care and treatment.

27. Plaintiff has suffered from mental anguish from the knowledge that she will have life-long complications as a result of the injuries she sustained from the use of Fosamax.

28. Plaintiff used Fosamax as prescribed and in a foreseeable manner.

29. As a direct and proximate result of using Fosamax, Plaintiff suffered severe bisphosphonate induced osteonecrosis and/or osteomyelitis of the jaw.

30. Plaintiff, as a direct and proximate result of using Fosamax, suffered severe and physical pain and suffering and has sustained permanent injuries and emotional distress. Plaintiff's injuries and damages exceed the jurisdictional amount required by this Court.

31. Plaintiff used Fosamax, which had been provided to her in a condition that was substantially the same as the condition in which it was manufactured and sold.

32. Based upon information and belief, the physician who supplied Fosamax to Plaintiff reasonably relied on the representations made to him by Merck prior to the

date of prescribing Fosamax for use. Based upon information and belief, the physician reasonably relied on the representations regarding the safety of Fosamax and would have altered his prescription habits by considering alternative treatments, altering his informed consent, and/or would not have recommended Fosamax if he had known the true facts regarding the safety of Fosamax. Thus, based on information and belief, had Plaintiff's physician known the true facts, the drug would not have been prescribed to Plaintiff because of one or more of the following: the physician would not have recommended Fosamax to Plaintiff and would have prescribed an alternative product; Plaintiff would have used the information provided by the physician and chosen an alternative medicine. In either event, Defendant's failure to provide true and accurate information to Plaintiff's physician, by omission and/or commission, was the proximate cause of Plaintiff's injuries.

33. Plaintiff would not have used Fosamax had Merck properly disclosed the risks associated with the drug. Alternatively, Plaintiff would have known the precursor events of osteonecrosis of the jaw and would have been able to avoid the clinical manifestation of the symptoms as they currently exist.

34. Prior to the dates upon which the aforesaid product was prescribed to Plaintiff, Merck knew, or should have known, that Fosamax was extremely dangerous and unsafe for use by the general public for the treatment and prevention of osteoporosis. Yet, Merck, through its affirmative misrepresentations and omissions, failed to take appropriate action to cure the nature of its defects and actively concealed from Plaintiff and her physician the true and significant risks associated with taking Fosamax. The



running of any applicable statute of limitations has been tolled by reason of Merck's fraudulent concealment.

35. As a result of Defendant's actions, Plaintiff and her prescribing physician were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this complaint, and that those risks were the direct and proximate result of Defendant's acts, omissions and misrepresentations.

**FIRST CAUSE OF ACTION**  
**[Strict Products Liability Failure to Warn]**

Plaintiff hereby incorporates by reference as if fully set forth herein each and every allegation in paragraphs 1 through 35, inclusive, of this Original Complaint, and for cause of action state that Defendant's conduct makes it strictly liable in tort for failure to adequately warn.

36. Defendant has engaged in the business of selling, distributing, supplying, manufacturing, marketing and/or promoting Fosamax, and through that conduct has knowingly and intentionally placed Fosamax into the stream of commerce with full knowledge that it would arrive in the judicial district where the Plaintiff ingested it. Defendant did in fact sell, distribute, supply, manufacture, and/or promote Fosamax to Plaintiff's pharmacy, Plaintiff's prescribing physician and ultimately, Plaintiff. Additionally, Merck expected the Fosamax it was selling, distributing and supplying, manufacturing and/or promoting to reach, and Fosamax did in fact reach, prescribing physicians and consumers throughout the United States, including Plaintiff, and Plaintiff's prescribing physician, without substantial change in the condition of the product.

37. At all times herein mentioned, the aforesaid product was defective and unsafe in manufacture, and was so at the time it was distributed by Defendant and ingested by Plaintiff. Specifically, the Fosamax ingested by Plaintiff was in a defective condition because Defendant distributed the product without adequate warning, failed to properly package the product and/or failed to label the product to give reasonable warnings of danger about the product. Given the severity of the adverse effects of Fosamax, the aforesaid product was defective in that it was not properly prepared and/or was not accompanied by proper warnings regarding all possible adverse side effects associated with the use of Fosamax. Thus, Merck failed to warn of a substantial danger not readily recognizable to an ordinary consumer, and the danger was known or knowable to Merck given the accepted scientific knowledge at the time of manufacture and distribution. These defects caused serious injuries to the user when Fosamax was used in its intended and foreseeable manner, i.e., when it was ingested as prescribed by Plaintiff's physician and in the manner recommended and/or marketed by Defendant.

38. Merck knew that the aforesaid product was to be used by the user without inspection for defects therein, and that the Plaintiff was among the class of persons that might foreseeably be harmed by the product Fosamax after its prescription, purchase and ingestion.

39. Plaintiff used the product for its intended purpose.

40. The aforesaid product was unaccompanied by warnings of its dangerous propensities that were known or reasonably scientifically knowable at the time of distribution. The reasonably foreseeable use of the product, i.e., ingestion to aid in the treatment of osteoporosis, involved substantial dangers not readily recognizable by the

ordinary, reasonably foreseeable user of the product. Merck failed to warn of the known or knowable likelihood of injury including, but not limited to the likelihood the user would develop osteonecrosis and/or osteochemonecrosis.

41. Plaintiff did not know, nor did Plaintiff have reason to know, at the time of the use of the aforesaid product, or at any time prior thereto, of the existence of the foregoing described defects. These defects and/or the failure to warn of these defects caused the herein described injuries to Plaintiff and the injuries from which the Plaintiff continues to suffer.

42. Merck knew that the aforesaid product was to be used by the user without inspection for defects therein and that the aforesaid product was unaccompanied by adequate warnings of its dangerous propensities that were known or reasonably scientifically knowable at the time of distribution.

43. Plaintiff neither knew, nor had reason to know, at the time of the use of the aforesaid product, or at any time prior thereto, of the existence of the foregoing described defects. Thus, Merck's failure to adequately warn Plaintiff and/or Plaintiff's physicians proximately caused Plaintiff's injuries.

**SECOND CAUSE OF ACTION**  
**[Strict Products Liability/Defective Product]**

Plaintiff hereby incorporates by reference as if fully set forth herein each and every allegation in paragraphs 1 through 43, inclusive, of this Original Complaint, and for cause of action state that Defendant Merck's conduct creates strict liability in tort because the Fosamax purchased and ingested by Plaintiff was a defective product.

44. Defendant Merck has engaged in the business of selling, distributing, supplying, manufacturing, marketing and/or promoting Fosamax, and through that

conduct has knowingly and intentionally placed Fosamax into the stream of commerce with full knowledge that it would arrive where Plaintiff purchased and ingested it. Merck did in fact sell, distribute, supply, manufacture, and/or promote Fosamax to Plaintiff and Plaintiff's prescribing physician. Additionally, Merck expected the Fosamax it was selling, distributing and supplying, manufacturing and/or promoting to reach, and did in fact reach, prescribing physicians and consumers in Plaintiff's home state, including Plaintiff, and her prescribing physician, without substantial change in the condition of the product.

45. The Fosamax manufactured and/or supplied by Merck was placed into the stream of commerce in a defective condition in that the foreseeable risks exceeded the benefits associated with the design or formulation and/or that the Fosamax was in a condition (a) that failed to perform as safely as an ordinary consumer would expect when used in an intended and reasonably foreseeable manner, or (b) the risk of danger inherent in the design of Fosamax outweighed the benefit of its design.

46. Alternatively, the Fosamax manufactured and/or supplied by Merck was defective in design or formulation in that when it was placed in the stream of commerce, it was more dangerous than an ordinary consumer would expect, and it was more dangerous than other forms of treatment.

47. The Fosamax manufactured and/or supplied by Merck was defective because Merck knew or should have known that the product created a risk of harm to consumers and that Merck failed to adequately warn of said risks.

48. The Fosamax manufactured and/or supplied by Defendant Merck was defective due to one or more of the following reasons:

- a. The product was not safe for ingestion as designed in that it caused permanent and/or progressive physical injury and other physical injuries;
- b. The product as designed and/or sold by Merck did not properly protect users from harm;
- c. The product caused Plaintiff to be exposed to harmful substances;
- d. The product was not safe for its intended use;
- e. The product as designed and/or distributed did not properly address various safety issues;
- f. The product was not tested properly or adequately;
- g. The risk of product usage for known and/or intended uses was outweighed by the risk of usage;
- h. The product had an inadequate warning;
- i. Merck failed its post-sale duty to warn of newly discovered harm;
- j. The product failed to perform as safely as an ordinary consumer would expect when used in an intended and reasonably foreseeable manner;
- k. The risk of danger inherent in the design of Fosamax outweighed the benefit of its design; and/or,
- l. The product was otherwise in a defective condition under applicable state law.

49. As designed, the Fosamax contained dangerous design defects and was not reasonably safe as intended -- making the risks of Fosamax outweigh its benefits and subjecting Plaintiff to risks which exceeded any alleged benefits of Fosamax.

50. The Fosamax manufactured and/or supplied by Merck was defective due, *inter alia*, to inadequate post-marketing warning or instruction because after Merck knew or should have known of the risk of injury from Fosamax, it failed to provide adequate warnings to users or consumers of the product and continued to promote the product improperly.

51. Plaintiff used the product for its intended and/or reasonably expected usage or purpose.

52. As a proximate and legal result of the defective condition of this product manufactured and/or supplied by Merck, Plaintiff was caused to suffer harm and the herein described injuries from which the Plaintiff continues to suffer. Thus, Merck's conduct proximately caused Plaintiff's injuries.

**THIRD CAUSE OF ACTION**  
**[Negligence and Gross Negligence]**

Plaintiff hereby incorporates by reference as if fully set forth herein each and every allegation in paragraphs 1 through 52, inclusive, of this Original Complaint.

53. At all times herein mentioned, Merck had a duty to properly design, manufacture, compound, test, inspect, package, label, distribute, market, examine, maintain, supply, provide proper warnings, and take such steps to assure that the product Fosamax did not cause users to suffer from unreasonable and dangerous side effects. Merck owed Plaintiff this duty. Merck breached this duty by:

- a. failing to properly and thoroughly test Fosamax before releasing the drug to market;
- b. failing to properly and thoroughly analyze the data resulting from the pre-marketing tests of Fosamax;
- c. failing to conduct sufficient post-market testing and surveillance of Fosamax;
- d. designing, manufacturing, marketing, advertising, distributing and selling Fosamax to consumers, including Plaintiff, without adequate warning of the significant and dangerous risks of Fosamax and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;
- e. failing to exercise due care when advertising and promoting Fosamax; and
- f. negligently continuing to manufacture, market, advertise, and distribute Fosamax after Merck knew or should have known of its adverse effects without providing an adequate warning of the known or knowable side-effects of Fosamax.

54. At all times herein mentioned, Merck knew, or in the exercise of reasonable care should have known, that the aforesaid product was of such a nature that if it was not properly manufactured, compounded, tested, inspected, packaged, labeled, distributed, marketed, examined, sold, supplied and prepared and provided with proper warnings, it was likely to injure the product's user.

55. Defendant Merck so negligently and carelessly manufactured, compounded, tested, failed to test, inspected, packaged, labeled, distributed,

recommended, displayed, sold, examined, failed to examine, and supplied the aforesaid product that it was dangerous and unsafe for the use and purpose for which it was intended.

56. Defendant Merck negligently failed to warn of the nature and scope of dangers associated with Fosamax.

57. Defendant Merck was aware of the probable consequences of the aforesaid conduct. Despite the fact that Merck knew or should have known that Fosamax caused serious injuries, it failed to disclose the known or knowable risks associated with the product as set forth above. Defendant Merck willfully and deliberately failed to avoid those consequences, and in doing so, Merck acted with a conscious disregard of the safety of Plaintiff and was therefore grossly negligent.

58. In all the above actions, Merck had a duty to act as a reasonable and prudent pharmaceutical manufacturer of a prescription drug, but breached this duty by failing to act as a reasonable and prudent pharmaceutical manufacturer of a prescription drug, and by breaching the standard of care proximately caused the Plaintiff to suffer physical injuries and other damages. As a result of the carelessness, negligence and gross negligence of Defendant Merck alleged herein and in such other ways to be later shown, the aforesaid product was a proximate cause of Plaintiff's injuries as herein alleged.

#### **FOURTH CAUSE OF ACTION [Breach of Implied Warranty]**

Plaintiff hereby incorporates by reference as if fully set forth herein each and every allegation in paragraphs 1 through 58, inclusive, of this Original Complaint.

59. At all times mentioned herein, Merck manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied and



sold the aforesaid product, and prior to the time it was provided to Plaintiff, Defendant impliedly warranted to Plaintiff that the product was of merchantable quality and safe for the use for which it was intended.

60. Plaintiff reasonably relied on the skill and judgment of Merck in using the aforesaid product.

61. The product was unsafe for its intended use and was not of merchantable quality, as warranted by Defendant in that it had very dangerous propensities when put to its intended use and would cause severe injury to the user. The aforesaid product was unaccompanied by warnings of its dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution. As a direct and proximate result of Merck's breach of warranty, Plaintiff sustained damages as alleged herein.

62. The aforesaid product did cause Plaintiff to sustain injuries and damages as herein alleged.

63. After Plaintiff was made aware that Plaintiff's injuries were a result of the aforesaid product, notice was impractical due to the nature of the injuries and thus, the filing of suit gives notice.

**FIFTH CAUSE OF ACTION  
[Breach of Express Warranty]**

Plaintiff hereby incorporates by reference as if fully set forth herein each and every allegation in paragraphs 1 through 63, inclusive, of this Original Complaint.

64. The aforementioned manufacturing, compounding, designing, distributing, testing, constructing, fabricating, analyzing, recommending, merchandizing, advertising, promoting, supplying and selling of the aforesaid product was expressly warranted to be safe for use by Plaintiff and other members of the general public.

65. Defendant Merck expressly warranted that Fosamax was safe. Upon information and belief, these warranties were included in numerous advertisements to the public, documents prepared for physicians, documents prepared for the public and were also spoken directly to physicians by agents of Defendant Merck. Upon information and belief, Defendant Merck knew or reasonably should have known that consumers would have directly reasonably relied on these representations and/or that consumers would have indirectly reasonably relied on these representations in that their physicians would reasonably rely on these representations, and that consumers would rely on the prescription advice of their physicians acting as either their agent, fiduciary or intermediary and who were directly acting based on these fraudulent representations.

66. Fosamax failed to conform to the Defendant's warranties because Fosamax was not safe.

67. At the time of the making of the express warranties, Defendant Merck had knowledge of the purpose for which the aforesaid product was to be used and warranted the same to be, in all respects, fit, safe, and effective and proper for such purpose. The aforesaid product was unaccompanied by warnings of its dangerous propensities that were either known or knowable at the time of distribution.

68. Upon information and belief, Plaintiff and Plaintiff's physicians reasonably relied upon the skill and judgment of Defendant Merck, and upon said express warranty, in using the aforesaid product. The warranty and representations were untrue in that the product caused severe injury to Plaintiff and was unsafe and, therefore, unsuited for the use for which it was intended. The aforesaid product could and did thereby cause Plaintiff to sustain injuries and damages as herein alleged.

69. As soon as the true nature of the product, and the fact that the warranty and representations were false, were ascertained, notice was impractical due to the nature of the injuries and thus, the filing of suit gives notice to Merck of the breach of said warranty.

70. As a direct and proximate result of the breach of these warranties, Plaintiff sustained personal injuries and other damages as alleged herein.

**SIXTH CAUSE OF ACTION  
[Fraud]**

Plaintiff hereby incorporates by reference as if fully set forth herein each and every allegation in paragraphs 1 through 70, inclusive, of this Original Complaint.

71. Defendant Merck falsely and fraudulently represented to Plaintiff, Plaintiff's physicians and members of the general public, that the aforesaid product was safe for use to aid in treating osteoporosis and was safer than other readily available treatments. The representations by Merck were, in fact, false. The true facts, include, but are not limited to, the fact that the aforesaid product was not safe for said purpose and was, in fact, dangerous to the health and body of Plaintiff.

72. The representations by Defendant Merck were, in fact, false. The true facts are that the product was not adequately tested, that there were frequent, severe, protracted, debilitating, difficult, life threatening and disabling side effects and adverse effects of the product, including, but not limited to, osteonecrosis and/or osteochemonecrosis of the jaw. Defendant did not disclose or warn Plaintiff or Plaintiff's physicians about the known risk of injury in using the product. Defendant misrepresented the safety of the product, represented that the product marketed was safe

for treating osteoporosis, and concealed warnings of the known or knowable risks of injury in using the product.

73. When Defendant Merck made these representations – about material facts - it knew that they were false. Defendant made said representations with the intent to defraud and deceive Plaintiff and with the intent to induce Plaintiff to act in the manner herein alleged. Upon information and belief, Defendant Merck knew or reasonably should have known that consumers would have directly reasonably relied on these representations and/or that consumers would have indirectly reasonably relied on these representations in that their physicians would reasonably rely on these representations, and that consumers would rely on the prescription advice of their physicians acting as either their agent, fiduciary or intermediary and who were directly acting based on these fraudulent representations.

74. At the time Merck made the aforesaid representations, and at the time Plaintiff took the actions alleged herein, upon information and belief, Plaintiff and Plaintiff's physicians were ignorant of the falsity of these representations, reasonably believed them to be true, and relied upon them. Upon information and belief, in reliance upon said representations, Plaintiff was induced to, and did, use the aforesaid product as herein described. Plaintiff's reasonable reliance on the deceptive statements resulted in Plaintiff's injuries.

75. If Plaintiff had known the actual facts, Plaintiff would not have taken such action.

76. The reliance of Plaintiff and Plaintiff's physicians on Defendant Merck's representations was justified and reasonable because said representations were made by individuals and entities that appeared to be in a position to know the true facts.

77. As a result of Merck's fraud and deceit, Plaintiff sustained the herein described injuries.

**SEVENTH CAUSE OF ACTION**  
**[Fraud by Concealment]**

Plaintiff hereby incorporates by reference as if fully set forth herein each and every allegation in paragraphs 1 through 77, inclusive, of this Original Complaint, and for cause of action alleges as follows:

78. At all times mentioned herein, Defendant Merck had the duty and obligation to disclose to Plaintiff and to Plaintiff's physicians, the true facts concerning the aforesaid product, specifically that said product was dangerous and defective and how likely it was to cause serious consequences to users, including injuries and death, and how unnecessary it was to use said product for the purposes indicated when considering alternative methods of treatment. Defendant made affirmative representations as set forth herein to Plaintiff, Plaintiff's physicians and the general public prior to the date Fosamax was provided to Plaintiff, while concealing material facts mentioned herein.

79. At all times mentioned herein, Defendant had the duty and obligation to disclose to Plaintiff and Plaintiff's physicians the true facts concerning the aforesaid product; that is, that use would cause injuries including but not limited to osteonecrosis and/or osteochemonecrosis.

80. At all times herein mentioned, Defendant Merck intentionally, willfully and maliciously concealed or suppressed the facts set forth herein from Plaintiff and Plaintiff's physicians with the intent to defraud as herein alleged.

81. At all times herein mentioned, neither Plaintiff nor Plaintiff's physicians were aware of the facts set forth above, and had they been aware of said facts, they would not have acted as they did, that is, would not have used the product.

82. As a result of the concealment or suppression of the facts set forth above, Plaintiff suffered injuries as set forth herein.

83. That at all times herein mentioned, Defendant intentionally and willfully concealed or suppressed the facts set forth herein from Plaintiff's physicians and therefore from Plaintiff, with the intent to defraud Plaintiff as herein alleged.

84. At all times herein mentioned, neither Plaintiff nor Plaintiff's physicians were aware of the facts set forth above, and had they been aware of said facts, they would not have acted as they did, that is, Plaintiff would not have ingested Fosamax.

85. As a proximate result of the concealment or suppression of the facts set forth above, Plaintiff suffered injuries as set forth herein.

#### **PUNITIVE AND/OR EXEMPLARY DAMAGES**

86. Clear and convincing evidence exists that the above described actions of Defendant Merck was committed oppressively, fraudulently or with malice or oppression. The wrongful conduct for which Plaintiff seeks punitive damages was committed knowingly and/or authorized or ratified by an officer, director or managing agent of the Corporation. Therefore, Plaintiff specifically requests that the Court submit jury

questions on issues of Defendant Merck's conduct to support punitive and/or exemplary damages in the maximum amount allowed by law.

### **COMPENSATORY DAMAGES**

87. As a direct and proximate result of the actions of Merck, Plaintiff has suffered the following damages in excess of the jurisdictional requirements of this court:

- a. Medical expenses incurred in the past and those reasonable and necessary expenses to be incurred in the future;
- b. Physical pain and suffering endured in the past and that likely to be suffered in the future;
- c. Mental anguish and emotional distress suffered in the past and that likely to be suffered in the future;
- d. Physical impairment suffered in the past and that likely to be suffered in the future;
- e. Disfigurement, past and future;
- f. Purchase costs;
- g. Such other damages to which Plaintiff is entitled in law or equity.

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff prays for relief from Defendant as follows:

88. In support of said damages, Plaintiff incorporates by reference all preceding and following paragraphs as if fully set forth herein and further alleges as follows:

- a) For general damages in a sum in excess of the jurisdictional minimum of this Court;

- b) For special damages in a sum in excess of the jurisdictional minimum of this Court;
- c) For compensatory damages in excess of the jurisdictional minimum of this Court;
- d) For consequential damages in excess of the jurisdictional minimum of this Court, according to proof;
- e) Medical, incidental, and hospital expenses according to proof;
- f) Future medical, incidental and hospital expenses according to proof;
- g) Prejudgment and post judgment interest as provided by law;
- h) Full refund of all purchase costs Plaintiff paid for Fosamax;
- i) Punitive damages;
- j) Attorneys' fees, expenses and costs of this action; and
- k) Such further relief as this Court deems necessary, just and proper

**DEMAND FOR JURY TRIAL**

92. Plaintiff demands a jury trial in this action.

DATED: 11/2/2007

Respectfully submitted,

By: Alexandra V. Boone  
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Alexandra V. Boone, Esq., TX SBN 00795259  
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